

CHANGES TO THE SPECIFICATION

Please substitute the following marked up paragraph(s) for the paragraph(s) now appearing in the currently filed specification:

On page 2, bridging page 3, paragraph 3:

a1 -- Figure 1 is a diagram illustrating a typical ultrasonic instrument known in the art in accordance with the '387 patent. As generally shown in Figure 1, a harmonic generator 1 provides electrical energy to the handpiece 2 ~~which~~ that imparts ultrasonic longitudinal movement to a surgical device, such as a sharp scalpel blade 3 ~~which~~ that is used for dissection and/or coagulation. The harmonic generator 1 includes a liquid crystal display device 4 indicating, e.g., the selected cutting power level as a percentage of the maximum available cutting power. The power selection level as well as other functions, such as coagulation mode duration, may also be selected by pushing buttons 5 in response to a menu appearing on the display 4. The handpiece 2 is connected to the harmonic generator 1 by a coaxial cable 8. As illustrated in more detail in Figure 1a and the '387 patent, the ultrasonic handpiece 2 houses an ultrasonic system for converting electrical energy to mechanical energy that results in longitudinal vibrational motion. The ultrasonic system comprises a transducer 9, a mounting device 10 and a surgical device 11 such as the scalpel blade and holder. The transducer 9 includes a stack of ceramic piezoelectric elements 12 with a motionless node at the center of the stack sandwiched between two aluminum cylinders 13 and 14. The transducer 9 is fixed to the mounting device 10 in a permanent manner. In turn, the mounting device 10 is attached to the housing at another motionless node by an integral ring 15. The mounting device 10, transducer 9 and the surgical device 11 are designed and fabricated to oscillate at the same resonant frequency, with each element tuned accordingly such that the resulting length of each such element is one-half wavelength. Expansion of the piezoelectric ceramic elements 12 results in the initiation of motion in the acoustic system of the transducer 9. --

[On page 3, paragraph 1:

92 -- Detachably connected to the harmonic generator 1 is a foot switch 6 for causing activation of the device in a coagulation operation mode. A switch 6a is incorporated in the handpiece 2. However, the switch 6a as found in the art includes shortcomings such as a high risk of inadvertent activation and deactivation. In addition, long-term ~~Long-term~~ operation results in fatigue in the finger of the human operator of the handpiece 2. --

[On page 5, paragraph 2:

93 -- Figure 1 is a diagram illustrating an ultrasonic surgical system ~~known in~~ in accordance with the prior art; --

[On page 5, paragraph 3:

94 -- Figure 1a is a diagram illustrating the interior of the ultrasonic surgical handpiece of the surgical system shown in Figure 1 ~~and known in the art~~; --

[On page 7, paragraph 1:

95 -- The generator console 510 includes a liquid crystal display device 512, which can be used for indicating the selected cutting power level in various means, such, as percentage of maximum cutting power or numerical power levels associated with cutting power. The liquid crystal display device 512 can also be utilized to display other parameters of the system. Power switch 511 is used to turn on the unit. While it is warming up, the "standby" light 513 is illuminated. When it is ready for operation, the "ready" indicator 514 is illuminated and the standby light goes out. If the unit is to supply maximum power, the MAX button 515 is depressed. If a lesser power is desired, the MIN button 517 is activated. This automatically deactivates the MAX button. The level of power when MIN is active is set by button 516. --

On page 7, bridging page 8, paragraph 2:

96 -- When power is applied to the ultrasonic hand piece by operation of either switch 534 or 540, the assembly will cause the end effector (surgical scalpel or blade) to vibrate longitudinally at approximately 55.5 kHz (or about 25 kHz in another embodiment), and the amount of longitudinal movement will vary proportionately with the amount of driving power (current) applied, as adjustably selected by the user. When a relatively high level of cutting power is applied, the blade is designed to move longitudinally in the range of about 40 to 100 microns at the ultrasonic vibrational rate. Such ultrasonic vibration of the blade will generate heat as the blade contacts tissue, i.e., the acceleration of the blade through the tissue converts the mechanical energy of the moving blade to thermal energy in a very narrow and localized area. This localized heat creates a narrow zone of coagulation, which will reduce or eliminate bleeding in small vessels, such as those less than one millimeter in diameter. The cutting efficiency of the blade, as well as the degree of hemostasis, will vary with the level of driving power applied, the cutting rate of the surgeon, the nature of the tissue type and the vascularity of the tissue. --

On page 9, bridging page 10, paragraph 1:

97 -- Figure 2b is a more detailed longitudinal cross-sectional view of an exemplary button switch according to the invention. This design, as well as others disclosed herein, allows for operation of the hand pieces in various modes, and is also described in related U.S. Patent Application Serial No. 09/693,549, commonly assigned to the same assignee as the present application, having the title RING CONTACT FOR ROTABLE CONNECTION OF SWITCH ASSEMBLY FOR USE IN AN ULTRASONIC SURGICAL SYSTEM and filed on October 20, 2000, which is incorporated herein by reference. The switch for use with an ultrasonic surgical handpiece according to the invention includes two independent switches under generally the same elastomer or flexible thin metallic skin with a middle recess for resting a finger of a human operator. The middle recess serves as a tactile reference point, as the blade and handpiece are non-symmetrically configured, for the human operator which avoids inadvertent activation or deactivation. In addition, the middle recess provides a safe, convenient spot for the human operator to grasp the handpiece and the switch without inadvertently activating the switch. The switch is also

ergonomically designed and tested to be comfortably ~~grasping for~~ grasped by small or big hands of any human ~~operator of that may operate~~ the handpiece.--

On page 12, paragraph 1:

-- Distally placing the switch on the handpiece according to the invention provides significant advantages over the prior art. As switches in the art are placed on the non-distal end (e.g., medial or proximal end) of the handpiece, blade control becomes ineffective since operating the blade with a switch proximally positioned on the handpiece creates substantially uncontrollable jitter when using the blade for cutting or coagulation on a tissue. Pressing the switches proximally located on the handpiece has negative effects and disrupts blade positioning on the tissue. ~~Such~~ This is particularly inconvenient for performing surgery and burdensome for a human operator in controlling the handpiece. Positioning the switches on the distal end of the handpiece significantly reduces the occurrence of blade jitter and generally improves operational control of the handpiece by the human operator. --

On page 13, ~~bridging page 14~~, paragraph 2:

-- Figure 3a is a cross-sectional view (taken at A-A of Figure 2) that illustrates a housing deflection embodiment of the switch for an ultrasonic surgical handpiece according to the invention. This one-push button design, as well as others disclosed herein, allows for operation of the hand pieces in various modes. The switch according to the housing deflection embodiment as shown in Figure 3a includes a pressure sensor 31 mounted inside the housing 33 of the ultrasonic handpiece 32 where it is relatively protected from the environment. The sensor 31, located on the internal side of a thin wall area 36 of the handpiece housing 33, detects pressure 30 applied by a finger of a human operator of the handpiece 32. The sensor 31 can be, but is not limited to, an electro-mechanical switch, a strain gauge, a pressure sensitive resistor/sensor combination, a hall ~~affect~~ effect device/magnet combination, reed switch/magnet combination, a piezo element, or a capacitance sensor which detects the force applied to the thin wall area 36. As finger pressure 30 is applied to the thin wall 36, the portion of the handpiece housing 33 at the thin wall 36 deflects, which is detected by the sensor 31. ~~The sensor 31 that~~ that outputs a response signal to the handpiece.

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This signal is conveyed through cable 526 to a detection circuit in the generator console 510 that controls the application of power to the transducers in the handpiece in response thereto. --

On page 18, paragraph 1:

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-- As an alternative, if no pressure is applied and sensors 45, 46 receive relatively equal field strengths, the handpiece can be off. It can then operate in one mode (e.g. cutting) as at different levels, as the lever is pressed toward sensor 45 and in a different mode (e.g. coagulation) at different levels as the lever is pressed towards sensor 46. --

On page 20, bridging page 21, paragraph 3:

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-- Accordingly, the invention provides a method for controlling an ultrasonic surgical handpiece using a switch located on the housing of the handpiece, which comprises the steps of: (1) monitoring the pressure applied to the housing a lever or ring compressors ~~the switch~~; (2) activating the surgical handpiece at a high power level if the monitored pressure reaches a high threshold; (3) operating the surgical handpiece at a corresponding intermediate power level if the monitored pressure reaches a specific intermediate threshold below the high threshold; and (4) deactivating the surgical handpiece if the monitored pressure is below a low threshold which is less than the specific intermediate threshold. The finger-operated switch includes, but is not limited to, (a) an electro-mechanical switch, (b) force sensitive resistors whose resistance is proportional to the force applied by the finger of the human operator of the surgical handpiece; (c) force sensitive capacitors whose capacitance is proportional to the pressure, deflection or compression of the insulation layer between two electrodes or is proportional to the spacing between the two conductive layers; (d) strain gauges mounted underneath or integral with the housing of the surgical handpiece such that the pressure applied thereto results in an output change in the strain gauges; (e) magnets or ferromagnets encased or embedded in an elastomer with a sensor inside the surgical handpiece that detects the field strength of the magnet and monitors changes relative to the force applied to the handpiece housing; and (f) piezo film or piezo ceramic materials whose charge or voltage is proportional to the force applied.--

On page 21, bridging page 22, paragraph 1:

912 -- Figure 5 is a flow diagram that illustrates the method according to the invention for controlling the ultrasonic surgical handpiece using a pressure-sensitive switch. In step 51, the pressure applied to the housing of the surgical handpiece, elastomer material mounted on the housing, an elastic lever, or an elastic ring is monitored. The monitored pressure is tested against a high threshold (step 52). If the monitored pressure does not reach the high threshold, the control flow reverts to step 51 which continues the monitoring of the pressure applied to the housing of the surgical handpiece. If the monitored pressure reaches the high threshold, the surgical handpiece is activated to operate at a first power level (step 53). If the surgical handpiece does not have multi-level operational capability (step 54), then control flow goes to step 57 and the monitored pressure is tested against a low threshold. If the monitored pressure reaches the low threshold, then the surgical handpiece is deactivated (step 58). This operation could also be based on a single threshold. In particular, if it is determined that the pressure has exceeded a minimum level, the power is fully turned on ~~full~~ and remains there until it is determined that the pressure has fallen below the single minimum threshold. --

On page 22, paragraph 1:

913 -- If the surgical handpiece can operate at multiple power levels (step 54), then in the method of Figure 4, the monitored pressure is tested against a plurality of specific thresholds (step 55). If the monitored pressure reaches a specific intermediate threshold, then the surgical handpiece operates at a power level corresponding to that specific threshold (step 56). In step 57, if the monitored pressure reaches the low threshold, then the surgical handpiece is deactivated. If the monitored pressure has not yet ~~reach~~ reached the low threshold, the control flow reverts back to step 55 and the surgical handpiece continues to operate at multiple power levels. --

On page 22, bridging page 23, paragraph 4:

914 -- Figure 6 is a diagram that illustrates a ring embodiment for the switch for the handpiece according to the invention. A harmonic generator 510, illustrated in Figure 2, provides

914 electrical energy to the handpiece 62 which imparts ultrasonic longitudinal movement to a surgical device, such as a sharp scalpel blade 603 used for dissection or coagulation. The handpiece 62 is connected to the harmonic generator 510 by the coaxial cable 26X. The ring switch 60a is a ring-like circumferential appendage on the handpiece 62, located near the distal end thereof. The handpiece 62 is activated when pressured is applied, e.g., by a finger of a human operator of the handpiece 62, to the side wall of the switch 60a. The mode of activation (e.g., cutting or coagulation) is determined by which side of the ring switch 60a is pressed upon. Pressure may be applied in a direction that is not perpendicular to the handpiece 62 and still activate it. Pressure applied to the top of the ring switch 60a which is perpendicular to the handpiece 62, depending on the particular embodiment, can lead to a number of functions. That is, the pressure applied to the top of the ring switch 60a may be ignored on the one hand, invoke a third mode of operation other than cutting and coagulation, or default to one of the two selectable modes of operation. For example, when the ring switch 60a is pressed, the base of the ring switch 60a applies pressure to one of several pressure-sensitive sensors which can activate the handpiece 62. One sensor 65 is activated when the ring switch 60a is pushed from one direction, another sensor 67 is activated when the ring is pushed from the other direction, and both sensors are activated when the ring is pushed upon from the above with a pressure force perpendicular to the handpiece 62.--

915 [On page 23, bridging page 24, paragraph 1:

-- The ring switch 60a can be mounted directly or indirectly to a single ~~sensors~~ sensor 69 such that when one side of the ring is pressed, the sensor is pushed upon. Conversely, when the opposing side of the ring is pushed, the sensor is pulled upon, or any pre-biased pressure is thereby reduced. Electronic circuitry in the sensor or handpiece can detect whether push or pull (or reduced pressure) is present and evoke a corresponding mode of operation in response. --

916 [On page 26, ~~bridging page~~ 27, paragraph 2:

917 -- Figure 7c is a partial cross-sectional view of yet another embodiment of the ring switch 60a (taken at C-C of Figure 6) for the handpiece 62 according to the invention. According to this particular embodiment, the ring switch 60a includes a capacitance transducer comprising, a center

91 ring 67, which is made of a conductive material such as a relatively inflexible metal, an outer layer of insulative ring 66 made of foam or elastomer, a conductive ring 65 which is an electrode made of a relatively flexible metal, another outer layer of insulative ring 68 also made of foam or elastomer on the other side of center ring 67, and another conductive ring 69 which is an electrode with an opposite polarity also made of a relatively flexible metal. When pressure 70A is applied to one side of the ring switch 60a, the insulative ring 66 is deflected and the foam or elastomer is depressed, which brings the conductive ring 65 closer to the center ring 67 and thereby reduces the capacitance in proportion to the pressure 70A as applied. The change in the capacitance between the conductive ring 65 and the center ring 67 activates the handpiece, causes the handpiece 62 to run in a specific mode of operation (such as cutting or coagulation), or proportionally increases the speed of operation depending on the amount of pressure 70A as applied. Conversely, when pressure 70B is applied to the other side of the ring switch 60a, the insulative ring 68 is deflected and the foam or elastomer is depressed, which brings the conductive ring 69 closer to the center ring 67 and thereby reduces the capacitance in proportion to the pressure 70B as applied. The change in the capacitance between the conductive ring 69 and the center ring 67 deactivates the handpiece, causes the handpiece 62 to run in a corresponding mode of operation (such as cutting or coagulation), or proportionally reduces the speed of operation depending on the amount of pressure 70B as applied.--

On page 31, paragraph 1:

91 -- Figure 7i is a partial cross sectional view of yet another embodiment of the ring switch 60a (taken at C-C of Figure 6) for the handpiece 62 according to the invention. According to this particular embodiment, the ring switch 60a includes a center ring 710 made of relatively flexible material, such as foam or elastomer, with two outer rings 713 and 714 which are relatively rigid or semi-rigid, and two relatively flexible rings 711 and 712 for supporting the center ring 710 with the outer rings 713 and 714. Inside the handpiece housing 63, two piezo rings 715A and 715B are fixed to the two sides of the bottom of the center ring 710 with the outer rings 713 and 714. The two piezo rings 715A and 715B are continuously or periodically monitored, i.e., stimulated using AC (alternating current) power near or generally close to the resonant frequency, for avoiding cross talk between the two piezo rings 715A and 715B. The resonant frequency or amount of energy needed

to maintain a given displacement is monitored. As pressure (70A or 70B) is applied to the center ring 710, these characteristics change (e.g., the resonant frequency and displacement), and that change is the basis for controlling the mode of operation of the handpiece 62. Alternatively, the pulse, amplitude, echo and timing of the response of the two piezo rings 715A and 715B as a result of the pressure applied (70A and 70B) are monitored, and subsequent Fast Fourier Transform (FFT) analysis can be performed. --

On page 31, bridging page 32, paragraph 2:

-- When pressure 70A is directly applied against the center ring 710 and indirectly against the piezo rings 715A and 715B, the ring switch 60a generates an output voltage proportional to the force applied (pressure 70A) and results in a polarity signal, thereby activating the hand piece 62, causing the handpiece 62 to run in a specific mode of operation (such as cutting or coagulation), or proportionally increasing the speed of operation depending on the amount of pressure 70A as applied. Conversely, when pressure 70B is directly applied against the center ring 710 and indirectly against the piezo rings 715A and 715B in the opposite direction, the ring switch 60a generates an output voltage proportional to the force applied (pressure 70B) and results in a different or opposing polarity signal, thereby activating the handpiece 62, causing the handpiece 62 to run in a specific mode of operation (such as cutting or coagulation), or proportionally decreasing the power or speed of operation depending on the amount of pressure 70B as applied. --

On page 35, bridging 36, paragraph 1:

-- Figures 10 and 10a are diagrams that respectively illustrate yet another embodiment and prototype for the ring switch 60a with activation zones 83A and 83B for the handpiece 62 according to the invention. The harmonic generator 510, illustrated in Figure 2, provides electrical energy to the handpiece 62 which imparts ultrasonic longitudinal movement to the surgical device 603 used for dissection or coagulation. The handpiece 62 is connected to the harmonic generator 510 by the coaxial cable 526. The ring switch 60a is a ring-like circumferential appendage on the handpiece 62, including the distal rib 84, a proximal rib 85, and two adjacent activation zones 83A and 83B therebetween, all located near the distal end of the handpiece 62. Human operators of the

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handpiece 62 can press their fingers against the surface of the activation zones (83A or 83B) and the finger pressure or force, which can be either perpendicular or non-perpendicular to the surface of the handpiece 62, is sensed and converted into an activation signal. The activation zones 83A and 83B are circumferential bands for sensing pressure for activating and deactivating the handpiece 62, changing the speed thereof (e.g., full or variable power), or running the handpiece 62 in specific modes of operation (e.g., cutting or coagulation). The distal rib 84 and the proximal rib 85 provide a tactile reference point for a human operator of the handpiece 62 relative to the activation zones 83A and 83B. The distal rib 84 and the proximal rib 85 are tapered to guide the fingers of the human operator of the handpiece 62 into the activation zones 83A and 83B. The distal rib 84 and the proximal rib 85 also provide finger support for the human operator that reduces inadvertent activation due to unwanted grasping contact with the activation zones 83A and 83B. Furthermore, the distal rib 84 or the proximal rib 85 can be transparent or translucent for indicating the activation status and mode of operation of the handpiece 62 by becoming illuminated during activation or changing colors according to the current mode of operation. --

On page 36, ~~bridging~~ page 37, paragraph 2:

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-- Figure 11 is a diagram that illustrates a further embodiment of the ring switch 60a with activation zones 87A and 87B for the handpiece 62 according to the invention. A harmonic generator 510, illustrated in Figure 2, provides electrical energy to the handpiece 62 which imparts ultrasonic longitudinal movement to a surgical device, such as a sharp scalpel blade 603 used for dissection or coagulation. The handpiece 62 is connected to the harmonic generator 510 by a coaxial cable 526. The ring switch 60a is a ring-like circumferential appendage on the handpiece 62, including two activation zones 87A and 87B with a divider 88 which is a recess or protrusion. The human operator of the handpiece 62 can press their fingers against the surface of the activation zones (87A or 87B) and the finger pressure or force, which can be either perpendicular or non-perpendicular to the surface of the handpiece 62, is sensed and converted into an activation signal. The activation zones 83A and 83B are circumferential bands for sensing pressure for activating and deactivating the handpiece 62, changing the speed thereof (e.g., full or variable power), or running the handpiece 62 in specific modes of operation (e.g., cutting or coagulation). The divider 88

920 provides a tactile reference point for a human operator of the handpiece 62 relative to the activation zones 87A and 87B. Furthermore, the divider 88 can be transparent or translucent for indicating the activation status and mode of operation of the handpiece 62 by becoming illuminated during activation or changing colors according to the current mode of operation. --

38 39 /
On page 37, bridging 38, paragraph 1:

Q2 -- Figure 12 is a diagram that ~~illustrate~~ illustrates an additional embodiment of the ring switch 60a with activation zones and sub-zones for the handpiece 62 according to the invention. A harmonic generator 510, illustrated in Figure 2, provides electrical energy to the handpiece 62 which imparts ultrasonic longitudinal movement to a surgical device such as a sharp scalpel blade 603 used for dissection or coagulation. The handpiece 62 is connected to the harmonic generator 510 by a coaxial cable 526. The ring switch 60a is a ring-like circumferential appendage on the handpiece 62, including a sliding barrier 90 and two activation zones 91 and 92 which are tape-like sensors that conform ~~on to~~ to the handpiece 62. A human operator of the handpiece 62 can press their fingers against the surface activation zones (91 or 92) and this force, which is generally perpendicular to the surface of the handpiece housing, is sensed and converted into an activation signal for activating and deactivating the handpiece 62, or for running it in various modes of operations (e.g., cutting or coagulation). The activation zones 91 and 92 are further divided into two respective groups of sub-zones (91A, 91B, 91C) and (92A, 92B, 92C), ~~respectively,~~ which, when pressed ~~upon,~~ activate additional modes of operation for the handpiece 62, e.g., variable power levels. The sliding barrier 90 wraps around the handpiece 62 and covers a portion of the activation zones 91 and 92, and more particularly, sub-zones 91A and 92A. The sliding barrier 90 shields sub-zones 91A and 92A to prevent activation, or to attenuate the pressure reaching the particular sub-zone. The sliding barrier 90 can be removably attached to the handpiece 62 which is snapped onto a desired position (e.g., over a particular sub-zone) if needed. The sub-zones allow flexibility of use of the handpiece 62 by providing specific, adaptable configurations of active zones and non-activation finger supporting zones (e.g., 91A and 92A) according to the preferences of the human operator of the handpiece. In addition, the sub-zones can be uniquely colored or numbered or otherwise marked for ready identification by the human operator. --